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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,366	01/15/2004	David C. Gordon	64093-087	5297

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MCDERMOTT, WILL & EMERY  
Suite 3400  
2049 Century Park East  
Los Angeles, CA 90067

EXAMINER
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BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3766

MAIL DATE	DELIVERY MODE
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06/07/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Interview Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/758,366	GORDON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mark W. Bockelman	3766	

All participants (applicant, applicant's representative, PTO personnel):

(1) Mark W. Bockelman. (3)\_\_\_\_\_

(2) Marc Brown. (4)\_\_\_\_\_

Date of Interview: 04 June 2007.

Type: a) ☒ Telephonic b) ☐ Video Conference  
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☐ No.  
If Yes, brief description: None.

Claim(s) discussed: None.

Identification of prior art discussed: Li et al.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Attached is a translation of the li et al document that the examiner relied upon in the last office action mailed 1-17-2007 as was previously requested by applicant..

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.



Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

PTO 07-4539

The People's Republic of China  
February 1999  
Article

PHARYNGOSCOPIC OBSERVATION DURING SLEEP IN PATIENTS WITH  
OBSTRUCTIVE SLEEP APNEA SYNDROME  
[阻塞性睡眠呼吸暂停综合症患者睡眠时咽腔观察]

Li Wuyi, et al

UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C.

May 2007

TRANSLATED BY SCHREIBER TRANSLATIONS, INC.

Translated Title : Pharyngoscopic Observation during Sleep in Patients with Obstructive Sleep Apnea Syndrome

Foreign Language Title : 阻塞性睡眠呼吸暂停综合症患者睡眠时咽腔观察

Authors : Li Wuyi, et al

Author Affiliation : the Chinese Academy of Sciences Peking Union Medical  
College Hospital

Source :

The obstructive sleep apnea syndrome, (OSAS) is a kind of diseases with high incidence. It is extensively recognized in last 20 years. The conventional surgery treatments adopt uvula and pharynx plastic operations. However, the objective curative effect is just about 50%. The cause is related with the diversified kinds of pharyngeal obstructions. The regular multi-channel sleep pictures only detect the nature but the positions and causes of the obstructions during sleep. Therefore, it has been tried to use x-ray jaw imaging, CT, MRI, pressure sensor, or endoscope, etc. to make the examination.<sup>[1]</sup> The examinations for sleeping patients are quite difficult and the results are not consistent. We tried to use the laryngofiberscope to observe the obstructions on sleeping OSAS patients. The preliminary results are given below.

## Materials and methods

### 1. Subjects

During 1994 and 1996, a period from May to August, 43 OSAS patients got the surgery operations in this hospital. Among them, 41 persons are males and 2 females. Their mean age was 47.7 (28~65 years old). Their BMI was  $29.5 \text{ kg/m}^2$  ( $24.4\sim36.6 \text{ kg/m}^2$ ). They were exclusively diagnosed as OSAS after 7 h of overnight PSG. Their mean RDI was 52 (7.2~105.7) and their mean minimum saturation oxygen was 62.6% (36~83%).

### II. Methods

Examination: The patients lay in dorsal segment and their nasal lumens and pharynges were treated with 1% pontocaine for superficial anesthesia. ENFT 3 Olympus laryngofiberscope (with suction apparatus,  $\phi$  6 mm) was inserted through nose, refer to

the method described by literature <sup>[2]</sup>. The end of device was located at the lower segment of soft palate margo iiber and the nasopharynx, respectively. The narrowing at three segments in nasopharynx is observed, i.e.: hyperpharynx (between the tongue base and epiglottis), oropharynx (middle tonsil) and velopharynx (the gap of airway lumen behind velum palatinum). The causes of obstructions were analyzed, such as, if there is any abnormality in soft palate, uvula, tongue base, pharyngeal wall, or tonsil, and their movements during the inspiration.

Observation procedure: (1) Muller inspiration examination during awakening: After the patient made several normal respirations, his/her mouth and nose were blocked after a deep inspiration. The collapses of each segment in airway lumen were observed. The process was repeated for 2 or 3 times. (2) Observation during sleep: We had tried to observe the sleeping patients in natural state or after injected with diazepam. However, the majority of them could not fell asleep or were awakened during the examination. Therefore, we used the method described in literature<sup>[2,3]</sup> that the sleep is induced by the intravenous injection of tranquillizer. Since disoprofol is characterized by its rapid effect and its small tranquiHzation dosage, the patients were intravenously transfused with 60~140 mg of it to induce sleep. All of the patients fall asleep immediately. When the obvious snoring was heard, the pharyngeal airway lumen was observed and no sleep interruption occurred. All the examinations were recorded with video tape. To guard against hypotension or apnea, the anesthetist was arranged to monitor the saturation oxygen, electrocardiogram and blood pressure so as to awaken the patient whenever necessary to avoid accident.

## Results

### I. Pharynx lumen obstructive segment

All the patients suffered from pathologic apnea and decrease of saturation oxygen in different extents. Total 90 obstructive segments were observed in 43 patients (43 in velopharynx, 28 in oropharynx and 23 in hyperpharynx). The velopharynx is the most common obstructive segment, which was found in all the patients. 79% of the patients were found obstructions in multi segments, among which, 12 patients were velopharyngeal obstruction + oropharyngeal obstruction (28%), 9 patients were velopharyngeal obstruction + hyperpharyngeal obstruction (21%) and 13 patients were velopharyngeal obstruction + oropharyngeal obstruction + hyperpharyngeal obstruction (30%). Only 9 patients were single velopharyngeal obstruction (21%). No single oropharyngeal obstruction or single hyperpharyngeal obstruction was found in the patients.

### II. The anatomical factors to cause the obstructions

In each segment of pharynx lumen, the obstructions may be caused by different anatomical factors, which are different from each other significantly. Therefore, the symptom of each obstruction is different. (1) Velopharynx: the collapse of pharyngeal wall during inspiration accounted for 26% (11/43), the posterior displacement of soft palate and uvula accounted for 33% (14/43) and both of them accounted for 42% (18/43). The above anatomical factors narrow or eliminate the posterior gap and cause the segmental obstruction. The redundant mucosa or pharyngeal wall, enlarged tonsil or lateral band of pharynx may exacerbate the obstruction. (2) Oropharynx: 28 patients



were found obstructions. The collapse was from lateral pharyngeal wall toward centerline. They were caused by the enlarged tonsil or the arcus alatoaryngeus, which eliminated the airway lumen diameter. (3) Hyperpharynx: Among the 23 patients with obstructions, 69% were caused by the thickened or posterior displacement of tongue base, which eliminates the airway lumen (16/23); 22% were caused by the pharyngeal wall collapse or enlarged tonsil (5/23), and 9% were caused by the enlarged tonsil, epiglottis edge relax or mucous membrane covering the pharynx entrance (2/23).

### III. The comparison between the examinations during sleep and awakening

The obstructed segment quantities found by Muller examination during awakening were less than during sleep. The pharyngeal obstruction positive rates found with the two methods, respectively, are: (1) Velopharynx: 91% (39/43) and 100 (43/43); (2) Oropharynx: 44% (19/43) and 65% (28/43); (3) Hyperpharynx: 30% (13/43) and 53% (23/43). The above results show that, sometimes, it is impossible to find the obstruction when sleep with Muller examination carried out during awakening, especially on the segments below the velopharynx.

## Discussion

We analyzed the pharyngeal obstructions of the OSAS patients during sleep with the observation. In those cases, the velopharynx was the most common obstructive segment (100%). But only 21% of the patents were obstructed at a single segment. Most of them were obstructed at the oropharynx and/or hyperpharynx (79%). The results show that the pharyngeal obstruction of OSAS patients were characterized by the obstructions in multi segments of airway lumen. Some researchers tried to find the exact

position of pharyngeal obstructions of OSAS with endoscopy and got the different results. Weitzman<sup>[6]</sup>, et al observed 4 sleeping patients with endoscopy and found the obstruction were located at velopharynx, exclusively. Borowleck,<sup>[7]</sup> et al, reported 10 cases that the obstructions were exclusively found at velopharynx and the obstructions were extended to oropharynx in some patients, but no obstruction was found in hyperpharynx. In the 12 patients observed by Rojewski, et al<sup>[8]</sup>, the airway lumen obstructions were mainly found in hyperpharynx, which were caused by the obstruction of larynx entrance due to the lower pharyngeal wall collapse. Croft, et al<sup>[4]</sup> examined 56 patients of snoring symptoms and OSAS patients with imidazole diazepam to induce sleep. It was found that 7 patients suffered no obstruction, 18 patients suffered the single velopharyngeal obstructions, 29 patients suffered both oropharyngeal and oropharyngeal obstructions and 2 patients suffered single hyperpharyngeal obstruction, which were caused by the tongue posterior displacement. Launois, et al<sup>[4]</sup> observed 45 OSAS patients under the diazepam induced sleep or natural sleep by the means of continuous positive airway pressure (CPAP) controlling pharyngeal muscle tension. It is found that the velopharyngeal obstruction accounted for 80%, mostly together with oropharyngeal and/or hyperpharyngeal obstructions, and the single oropharyngeal or hyperpharyngeal obstructions accounted for 20%.

It is important to analyze the obstructive segments in clinical medicine. It is well known by the experts that, based on the requirements of surgery operations, it is necessary to divide the OSAS patients into two categories, i.e. the single velopharyngeal obstruction and the obstruction below velopharynx (especially, at hyperpharynx). The plastic operation is effective to the former and the latter is better to be treated with CPAP

or more extensive operations for relieving the obstructions in different segments<sup>[3~5,8,9]</sup>. Based on the above theories, Riley, et al.<sup>[8]</sup>, adopted diversified operations, such as velopharynx plastic operation, palate nod antedisplacement, posterior tongue bone suspending, or upper and lower jawbones antedisplacement, etc. to treat 306 OSAS patients. 95% of them normalized their respiratory disturbance indexes and minimum saturation oxygen after the operations. The curative effect is similar as CPAP.

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The anatomical causes to the obstructions in different segments are different. At the same segment of pharynx lumen, the obstruction may be caused by the different anatomical abnormalities. For example, some of the velopharyngeal obstructions are caused by the soft palate or uvula posterior displacement, and some are caused by pharyngeal wall collapses, or by both of them. The redundant mucosa of pharynx, enlarged tonsil or lateral bends of pharynx is also the factor to exacerbate the obstructions. Therefore, it is necessary to arrange different operation to different patient based on his/her individual physical condition. The single excision of soft palate or uvula cannot relieve the velopharyngeal obstruction caused by the pharyngeal wall collapse, let alone the oropharyngeal obstruction or hyperpharyngeal obstruction. Fujita<sup>[9]</sup> adopted laser tongue centerline plastic operation to treat the OSAS patients with hyperpharyngeal obstructions. It has good curative effect to the patients with single tongue base posterior displacement. The failures were mainly due to that the operation could not correct the lower pharyngeal wall collapse.

The Muller inspiration examination during awakening is the conventional simple method to diagnose the obstructions in pharynx. However, it has some limitation since

the diagnosis of oropharynx and hyperpharynx during awakening is much more different than during sleep. Croft, et al<sup>[2]</sup> 28 found that patients suffered oropharyngeal and hyperpharyngeal obstructions during sleeps, but Muller examination only verified 14 cases. The reason is that, during sleep, the actions and tensions of the tongue muscles and pharyngeal muscles influenced the observation of airway unblockedness.